

Media Release



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US FDA joint advisory committee recommends approval of weight loss drug Orlistat 60mg capsules for over-the-counter use

Low-dose orlistat has potential to be the only FDA-approved weight-loss treatment
available over-the counter in US

Roche announces that the U.S. Food and Drug Administration's (FDA) joint Nonprescription Drugs and Endocrinologic and Metabolic Drugs Advisory Committee recommended (11 to 3) that orlistat 60 mg capsules be approved for over-the-counter use in the United States to promote weight loss in overweight adults, when used along with a reduced calorie, low-fat diet. If approved by FDA, OTC orlistat, which GlaxoSmithKline Consumer Healthcare proposes to market under the brand name Alli (pronounced AL-eye), would be the only FDA-approved weight loss drug available over the counter. Alli would be indicated for use by overweight adults along with a reduced calorie, low-fat diet.

GlaxoSmithKline Consumer Healthcare currently promotes prescription Xenical (orlistat 120mg) in the U.S. following an agreement with Roche. Xenical will remain available by prescription for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet and to reduce the risk for weight regain after prior weight loss in patients with an initial body mass index (BMI) ≥ 30 kg/m² or ≥ 27 kg/m² in the presence of other risk factors (eg, hypertension, diabetes, dyslipidemia). Xenical will continue to be marketed by Roche under the throughout the rest of the world.

The safety and efficacy of Xenical, which has been marketed as a prescription drug in the U.S. since 1999, is supported by more than 100 controlled clinical studies conducted in more than 30 countries, including the four-year landmark XENDOS trial, the longest study ever of a weight loss medicine, which demonstrated a reduced risk of progressing to diabetes. Xenical has been used in

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more than 22 million patient treatments in 145 countries

Orlistat is a weight-loss medication that works locally in the gut by inhibiting the absorption of dietary fat and does not act centrally. Orlistat should be used in conjunction with a reduced calorie diet that contains no more than 30 percent of calories from fat. Following such a diet maximizes weight loss and minimizes unwanted gastrointestinal treatment effects. Help and advice on adopting a healthy eating plan will be provided in the Alli program.

About the Overweight Population

In recent years, while the prevalence of the US population being overweight has consistently remained around 30%, the prevalence of obesity has risen steadily.¹ Research suggests that overweight individuals appear to be on the pathway to obesity,^{2,3} a condition that is associated with an increased risk of developing health problems such as hypertension, type 2 diabetes and heart disease.⁴ Factors that can contribute to being overweight include an abundance of high-calorie foods, low levels of physical activity, behavior, environment, and genetics.⁵ Currently, 65 percent (or approximately 130 million) of U.S. adults are overweight or obese, according to the National Institutes of Health.⁶

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Additional information

- Roche Health-Kiosk, Overweight: www.health-kiosk.ch/start_uebg.htm
- Managing your weight: www.roche-obesity.net
- About GlaxoSmithKline: www.gsk.com

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¹ Hedley AA, Ogden CL, Johnson CL, Carroll MD, Curtin LR, Flegal KM. Prevalence of overweight and obesity among US children, adolescents, and adults 1999-2002. *JAMA* 2004;291:2847-2850.

² Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and trends in obesity among US adults, 1999-2000. *JAMA* 2002;288:1723-1727.

³ McTigue KM, Garrent JM, Popkin BM. The natural history of the development of obesity in a cohort of young US adults between 1981-1998. *Ann Intern Med* 2002;136:857-864.

⁴ Centers for Disease Control and Prevention: "Overweight and Obesity." <http://www.cdc.gov/nccdphp/dnpa/obesity/>. Accessed 12/22/05.

⁵ Centers for Disease Control and Prevention. "Overweight and Obesity: Contributing Factors." http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm. Accessed 12/22/05.

⁶ U.S. Department of Health and Human Services "Statistics Related to Overweight and Obesity." <http://win.nidk.nih.gov/statistics/ovrwt/> Accessed 12/22/05.